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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/849,395	05/07/2001	Yasuo Sakai	SUD-001-USA-CIP	9441

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EXAMINER
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NICKOL, GARY B

ART UNIT	PAPER NUMBER
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1642

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DATE MAILED: 05/14/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application N .

09/849,395

Applicant(s)

SAKAI ET AL.

Examin r

Gary B. Nickol Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 11 March 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-7 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-7 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

***Response to Amendment***

The Amendment filed March 11, 2003 (Paper No. 10) in response to the Office Action of September 5, 2002 is acknowledged and has been entered.

Claims 6-7 were added.

Claims 1-7 are pending and are currently under consideration.

**The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.**

***Claim Objections***

The amendment to rectify spelling errors in the Claims is improper. Applicants inserted the correct spellings but failed to delete the corresponding misspelled words. For example, the last line of Claim 5 now reads "and n being a natural munber number".

All claims being currently amended shall be submitted with markings to indicate the changes that have been made relative to the immediate prior version of the claims. The changes in any amended claim should be shown by strikethrough (for deleted matter) or underlining (for added matter). No separate "clean" version should be submitted for currently amended claims, as this requirement has been eliminated. Markings should only be made in claims being currently amended in an amendment paper. (Published in the OG, February 25, 2003).

**Rejections Maintained:**

Claim 5 remains rejected and new Claim 7 is rejected under 35 U.S.C. 102(b) as being anticipated by Thakur *et al.* (Biopolymers, Vol.25, 1986, pages 1081-1086) for the reasons of record in Paper No. 8, page 6.

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Applicants argue (Paper No. 10, pages 26-27), that in contrast to the peptide described by Thakur *et al.*, the stabilizer peptide is not bonded with any compound, and is only one peptide chain. Applicants further argue that the peptide does not have a triple helix structure. Applicants further add that the transition temperature is not observed. This argument has been considered but is not found persuasive because arguments that rely on a particular distinguishing features are not persuasive when those features are not recited in the claims. Narrow limitation contained in the specification cannot be inferred in the claims where the elements not set forth in the claims are linchpin of patentability. See *In re Philips Industries, Inc. v. State Stove & Mfg. Co.*, 522 F.2d 1137, 186 USPQ 458 (CA6 1975), 237 PTJA A-12. While the claims are to be interpreted in light of the specification, it does not follow that limitations from the specification may be read into claims. On the contrary, claims must be interpreted as broadly as their terms reasonably allow. See *Ex parte Oetiker*, 23 USPQ2d 1641 (BPAI, 1992). Applicant is reminded that the claims define the subject matter of his invention and that the specification cannot be relied upon to read limitations into the claims. Thus, applicant's arguments have not been found persuasive and the rejection is maintained.

**New Rejections/Objections:**

Claims 1-2, and 4-7 are rejected under 35 U.S.C. 102(b) as being anticipated by Sakai Yasuo (JP 07082299, March 28, 1995, English translation included).

Sakai Yasuo teaches a method for producing a nonantigenic peptide composition comprising a decomposing step comprising specifically decomposing gelatin or collagen using collagenase to form a decomposed gelatin or collagen, and a purifying step comprising purifying

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the decomposed matter to obtain a nonantigenic peptide composition, wherein the nonantigenic peptide composition has a molecular weight of not more than 20,000 Da and an amino acid sequence of  $(\text{Gly-X-Y})_n$  where  $n$  is a natural number. Further, Sakai Yasuo teaches a nonantigenic peptide obtained by filtration wherein the nonantigenic peptide has a molecular weight greater than 0 and not more than 20,000 Da and having an amino acid sequence of  $(\text{Gly-X-Y})_n$  where  $n$  is a natural number (see pages 2, 8-9). Yasuo further teaches wherein said decomposing step is performed by a column process (page 12) and wherein said purifying step is performed by reversed phase chromatography (page 24).

Although Sakai Yasuo does not disclose the use of the peptide as a stabilizer, the ability to function as a stabilizer would be an inherent property of the disclosed peptide as the intended use of the compound must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. A composition is a composition irrespective of what its intended use is. See In re Tuominen, 213 USPQ 89 (CCPA 1982).

Applicants argue (Paper No. 10, pages 22-23) that the named inventor of the Japanese patent (JP 07082299) is the inventor of the present application. This argument has been considered but is not found persuasive because, upon reconsideration, the reference is a statutory 102(b). See MPEP 706.02 under Determining the Effective Filing Date.

Applicants further argue that the peptide in the prior art is an insufficient stabilizer and refer to an abstract (Bio. Bull, 1998) wherein it appears that applicants are arguing that peptides of less than 1000 in MW are excluded as stabilizers. First, it should be noted that no abstract was

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furnished with the Office. Secondly, the reference is anticipatory. Any arguments that the peptide of the prior art is unsatisfactory or disadvantageous are not persuasive because arguments that rely on a particular distinguishing features are not persuasive when those features are not recited in the claims. Applicant is reminded that the claims define the subject matter of his invention and that the specification *cannot* be relied upon to read limitations into the claims. Applicants further argue that whether the molecular weight is 1,000 or 2,000 is important for the yield and it is important whether the peptide is known as a stabilizer. Applicants further argue that it can be seen from the foregoing that the prior art did not produce the peptide which is both nonantigenic and acted as stabilizer. This argument has been considered but is not found persuasive for the reasons of record. The intended use of the compound (i.e. as a stabilizer) must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. As set forth in the claims, the upper limitation for the peptide is 20,000 Daltons which is clearly anticipated by the prior art. Further, Applicants' arguments directed to In Re Thorpe are now considered moot since the prior art did disclose reversed-phase high performance liquid chromatography. Thus, applicant's arguments have not been found persuasive and the rejection is maintained.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sakai Yasuo (JP 07082299, March 28, 1995) in view of Current Protocols in Molecular Biology (Vol.2, Chapter 10, Pages 10.1.1- 10.18.6, 1990, Provided in Paper No. 8)

Sakai Yasuo teaches as set forth above and further teaches (page 13, line 3) that methods for separating the raw material/collagenase and the degradation product are based on differences in molecular weights.

Sakai Yasuo differs from the instant invention by not employing gel filtration.

Current Protocols teaches that gel filtration is common procedure known in the prior art for protein purification (page 10.9.1) wherein differences in molecular weight determine the fraction range (10.9.7).

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made and one would have been motivated to apply gel filtration to purify the composition taught by Sakai Yasuo with a reasonable expectation of success as such purification procedures were well known and standard procedures in the art as taught by Current Protocols.

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Applicants argue (Paper No. 10, page 28) that peptide of the present invention has both nonantigenic and stabilizer properties which has not been disclosed by the prior art. This argument has been considered previously and has not been found persuasive. Thus, applicant's arguments have not been found persuasive and the rejection is maintained.

Claim 7 is objected to in the last line of the claim for reciting "X and Y" as it appears that the claim has not been properly amended to reflect that X and Y are any amino acid residue.

**All other rejections and or objections are withdrawn in view of applicant's amendments and arguments there to.**

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gary B. Nickol Ph.D. whose telephone number is 703-305-7143. The examiner can normally be reached on M-F, 8:30-5:00 P.M..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa can be reached on 703-308-3995. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-308-4242 for After Final communications.



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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Gary B. Nickol, Ph.D.  
Examiner  
Art Unit 1642

GBN  
May 8, 2003

A handwritten signature in cursive script, appearing to read "Gary B. Nickol", written in black ink.